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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/028,400 | 12/20/2001 | Diana Zanini | VTN-568 | 3607 |
| 27777 7590 07/19/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | EXAMINER CHOI, FRANK I | |
| | | | ART UNIT 1616 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/028,400

Applicant(s)

ZANINI ET AL.

Examiner

Frank I. Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/23/2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,14-17,19 and 21-75 is/are pending in the application.
- 4a) Of the above claim(s) 25-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-11,14-17,19,21-24 and 55-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/18/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

The Examiner withdraws the restriction requirement as to claims 55-72, i.e. groups I-VI. The election of species requirement is maintained, i.e. formula I. As such, claims 1, 4-11, 14-17, 19, 21-75 are pending with claims 25-54 withdrawn as directed to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55-61, 63-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05-269181 or EP 1 050 314, each in view of the acknowledged prior art, Vanderlaan et al. (US Pat. 5,998,498), Laskey (US Pat. 3,929,741), JP 55-38855, Malecki et al., Tilley, Bennett and Young et al..

JP 05-3269181 teaches an antimicrobial soft contact lens comprising an antimicrobial substance, such as an acrylacetate or benzoyl acetate complex of silver, ranging from 0.1 to 20% by weight, polymers of monomers, which include vinyl, allyl group, acrylic groups and/or methacrylic groups, including acryloyloxyethyl phthalic acid, acryloyloxyethyl succinate and methacryloyloxyethyl succinate, phenyl acrylate, phenyl methacrylate, benzy methacrylate and acrylamide (paragraphs 0009-0012, 0024-0026). Specific examples of soft contact lenses are taught containing 69.7 w% 2-hydroxyethyl methacrylate, 24.6 w% methyl methacrylate, 0.4 w% ethylene glycol dimethacrylate and 5w% silver acrylacetate or 5w% silver benzoyl acetate

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(paragraphs 0052-0055). It is taught that the amount of the antibacterial substance to be added depends on the maintenance of transparency and antimicrobial activity (paragraph 0028).

EP 1 050 314 disclose an antimicrobial contact lens containing silver, in an amount such that preferably no other separate disinfection procedure is necessary, where the polymeric material may comprises polymers which are synthetic, naturally occurring, or combination thereof, including silicone polymers, polyolefins, polyesters, poly urethanes, acrylic, hydrogel-forming polymers, polycarbonates and combinations thereof, including poly-HEMA, polyacrylimide, polydimethyl siloxane, PVP, silicone-acrylate or other hydrophilic contact lens material and the like, provided that the polymer or copolymer should be optically clear and otherwise useful as a contact lens material (Paragraphs 0042-0043, 0048, 0051). It is disclosed that the antimicrobial metal ion is present in a concentration from about 0.01 to 5wt. % of the zeolite which is present in the polymer in a concentration of about 0.01 to 5wt.% (Paragraph 0038).

Applicant acknowledges that soft contact lenses based on hydrogels are widely used because they are more comfortable but that extended use encourages the build of bacteria and other microbes (Pg. 1). It is acknowledged that examples of these soft contact lens, include etafilcon A, balafilcon A, aquafilcon A, lenefilcon, lotrafilcon and silicone hydrogels (Pg. 20, lines 1-8).

Vanderlaan et al. teach that soft contacts can be prepared from silicone hydrogels which combine silicone containing monomers and hydrophilic monomers (See entire reference, especially column 5).

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Laskey teaches that hydrophilic monomers of acrylamido sulfonic acid or sulfonate are suitable for soft contact lenses and have greater water retention and because of a greater ability for cross-linking have increased flexibility in the modification of physical properties (Column 1).

JP55-38855 disclose that 2-acryl amide-2-methyl propane sulfonic acid binds with antimicrobial metal, such as silver, which when formulated into films, including porous films, provides a time-releasable antimicrobial material having long-term effectiveness. It is disclosed that monomers copolymerizable with the binding monomer can be selected from a wide range according to the application of the producing antimicrobial material, and include ethylene, propylene, vinyl chloride, vinylidene chloride, vinyl acetic acid, acrylic acid ester, methacrylic acid ester, styrene, butadiene, acryl amide, aryl compound. It is disclosed that the antimicrobial metallic ions can be introduced by bringing the product in contact with said metal ions, for example soaking the product in an aqueous solution of silver nitrate for 20 minutes (See entire English translation of JP 55-38855, especially Pgs. 2-6, 9-13 thereof).

Malecki et al. disclose methods of determining stability constants of silver with various ligands and that antibacterial activity is related to solubility (Abstract).

Tilley disclose determination of stability constants of various complexes with silver (Abstract).

Bennett discloses that good movement is one of the factors important for good contact lens performance (Abstract).

Young et al. discloses tests for determining contact lens movement (abstract).

The prior art discloses the complexes of silver with ligands and contact lenses containing the same. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an antimicrobial contact lens comprising silver and a polymer

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comprising a monomer of formula I. However, the prior art amply suggests the same as antimicrobial soft contact lenses containing silver and monomers falling within the scope of formula I are disclosed by the prior art. As such, it would have been well within the skill of one of ordinary skill in the art to have been motivated to modify the prior art as above with the expectation the soft contact lenses produced would have antimicrobial properties and be time-releasable while having long-term effectiveness and, thus, avoid the problems associated with extended wear. Further, it would have been well within the skill of one of ordinary skill in the art to determine the stability constant of a given silver complex with the binding monomer with the expectation that the relative antimicrobial activity could be predicted. Furthermore, it would have been well within the skill of one of ordinary skill in the art to prepare the antimicrobial lens by soaking the lens containing the binding monomer in an aqueous solution containing the silver ions with the expectation that the silver ions would bind with the binding monomers contained in the contact lens. Finally, it would have been well within one ordinary skill in the art to assess contact lens movement with the expectation that determining lens movement would facilitate good contact lens performance.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 55-61, 63-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05-269181 or EP 1 050 314, each in view of the acknowledged prior art, Vanderlaan et al. (US Pat. 5,998,498), JP 55-048855, Malecki et al., Tilley, Bennett and Young et al., and either Mueller (US Pat. 5,011,275) or Rostoker et al. (US Pat. 4,038,264).

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JP 05-3269181, EP 1 050 314, the acknowledged prior art, Vanderlaan et al., JP 55-038855, Malecki et al., Tilley, Bennett and Young et al. are cited for the same reasons as above and are incorporated herein to avoid repetition.

Mueller discloses a copolymer having high clarity, high hydrophilicity, high oxygen permeability which, in the water swollen state, is soft and flexible, which is suitable for use in soft contact lenses and preferably contains 0.1-10 percent by weight of an ethylenically unsaturated sulfonic acid, such as 2-methacrylamido-2-methyl propane-sulfonic acid (Column 3, Column 4, lines 1-43, Column 12, lines 6-22, Column 6, lines 19-23).

Rostoker et al. disclose that minor amounts of sodium 2-acrylamide-2-methylpropane sulfonic acid, up to 40 percent by weight, to modify the properties of a water-insoluble, hydrophilic polymer which is especially suitable for preparing contact lenses (Column 1, Column 2, lines 1-25, Column 9, Column 10).

The prior art discloses the complexes of silver with ligands and contact lenses containing the same. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an antimicrobial contact lens comprising silver and a polymer comprising a monomer of formula I. However, the prior art amply suggests the same as antimicrobial soft contact lenses containing silver and monomers falling within the scope of formula I are disclosed by the prior art. As such, it would have been well within the skill of one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the soft contact lenses produced would have antimicrobial properties and be time-releasable while having long-term effectiveness and, thus, avoid the problems associated with extended wear and that minor amounts of 2-acrylamide-2methylpropane sulfonic acid can be used to modify the properties of the polymer as desired with the expectation of arriving at a

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polymer suitable for use in contact lens. Further, it would have been well within the skill of one of ordinary skill in the art to determine the stability constant of a given silver complex with the binding monomer with the expectation that the relative antimicrobial activity could be predicted. Furthermore, it would have been well within the skill of one of ordinary skill in the art to prepare the antimicrobial lens by soaking the lens containing the binding monomer in an aqueous solution containing the silver ions with the expectation that the silver ions would bind with the binding monomers contained in the contact lens. Finally, it would have been well within one ordinary skill in the art to assess contact lens movement with the expectation that determining lens movement would facilitate good contact lens performance.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over by JP 55-048855 in view of Ulmer et al. (US Pat. 3,822,780).

JP 55-048855 is cited here for the same reasons as above and is incorporated herein to avoid repetition.

Ulmer et al. disclose a contact lens case that can be made from olefin polymers such as polyethylene or polypropylene and which contain supports which are perforated to facilitate circulation of liquid for proper sterilization and facilitating cleaning (Column 2, lines 25-41).

The prior art discloses complexes of silver with sulphonic acid ligands and polymer articles containing the same. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a contact lens case formed from a polymer containing a monomer of formula I. However, the prior art amply suggests the same as the prior

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art discloses that 2-acrylamide-2methylpropane sulfonic acid is able to bind with silver and polymerize with other monomers, including ethylene or propylene, to form polymer articles having antimicrobial activity. As such, it would have been well within the skill of one of ordinary skill in the art to prepare the contact lenses cases by polymerizing ethylene or propylene with the 2-acrylamide-2methylpropane sulfonic acid and contacting the same with silver with the expectation that upon contact with aqueous liquids that the silver ions will be slowly released and provide antimicrobial activity to disinfect contact lenses while in storage in the contact lens case.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1,4-11,14-17, 19, 21-24,55-61, 68-70, 73-75 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/703,770 or claims 1-27 of copending Application No. 10/734,762. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending applications disclose a method of preparing antimicrobial contact lenses wherein the antimicrobial contact lenses contain the same monomers and antimicrobial silver, and preparation of the contact lens by soaking the contact lens containing said monomers in an aqueous silver solution, such as a silver nitrate for a period of at least 20 minutes, as that claimed in the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

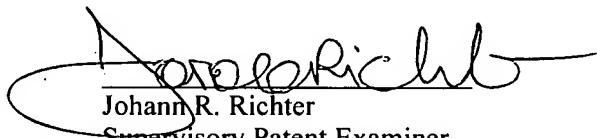
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
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July 9, 2007


Johann R. Richter
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